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ATTORNEY DOCKET NO.: 2003080-0142 (SK-893-B-US)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Danishefsky *et al.* Examiner: Karen A. Canella  
Serial No.: 10/728,041 Art Unit: 1642  
Filing Date: December 3, 2003  
Title: CLUSTERED MULTI-ANTIGENIC CARBOHYDRATE CONSTRUCTS,  
METHODS FOR THEIR PREPARATION, AND USES THEREOF

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**TRANSMITTAL**

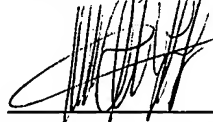
In regard to the above-referenced patent application, enclosed please find the following:

1. Statement Filed Pursuant to the Duty of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98 (6 pages);
2. Form PTO-1449 (2 pages.);
3. Cited Art (10 References); and
4. Return-Receipt Postcard.

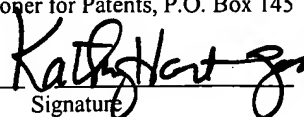
If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,  
CHOATE, HALL & STEWART

Dated: January 26, 2005

  
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Nadège M. Lagneau, Ph.D.  
Reg. No. 51,908

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Certificate of Mailing	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 145 Alexandria, VA 22313-1450	
January <u>28</u> , 2005	
Date	Signature
_____ Kathy Hart Gagnon	
Typed or Printed Name of person signing certificate	



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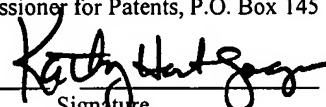
**STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE  
UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants  
request consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or  
☒ A *supplemental* Information Disclosure Statement.

<b>Certificate of Mailing</b>	
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January <u>28</u> , 2005	
Date	Signature
Kathy Hart Gagnon	
Typed or Printed Name of person signing certificate	

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☒ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

☒ A copy of each cited reference not indicated with a † is included;

☐ Copies of references indicated with a † on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

☐ Copies of English translations of one or more non-English references are included.

Applicants hereby make the following additional information of record in the above-identified application:

Applicants certify that the Information Disclosure Statement *either*:

☒ Does not contain non-English language citations;

☐ Does contain non-English language citations, of which the following is a concise

explanation:

- [ ] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

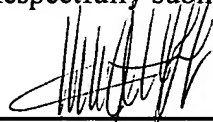
The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,



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Nadège M. Lagneau, Ph.D.

Reg. No. 51,908

Date: January 26, 2005

PATENT DEPARTMENT  
CHOATE, HALL & STEWART  
Exchange Place  
53 State Street  
Boston, Massachusetts 02109  
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Fax: (617) 248-4000

<b>Form PTO-1449</b> (REV. 10-03)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket 2003080-0142 (SK-893-B-US)		In re Application No. 10/728,041	
<div style="display: flex; align-items: center; justify-content: center;"> <div> <b>INFORMATION</b>  <b>DISCLOSURE STATEMENT</b>  <i>(Use several sheets if necessary)</i> </div> </div>				Applicant: Danishefsky <i>et al.</i>			
				Filing Date: December 3, 2003		Group: 1642	

U.S. PATENT DOCUMENTS					
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Sub class

U.S. PATENT APPLICATIONS					
Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:

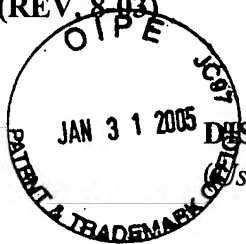
  

FOREIGN PATENT DOCUMENTS					
Examiner's Initials	Document No.	Country	International Publication Date	Translation	
				Yes	No
	WO 97/03995	WIPO	February 6, 1997		

OTHER DOCUMENTS	
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Chen <i>et al.</i> , "Exploration of Modalities in Building a $\alpha$ -O-Linked Systems Through Glycal Assembly: A Total Synthesis of the Mucin-Related F1a Antigen" <i>J. Am. Chem. Soc.</i> , <b>120</b> , 7760-7769, 1998.
	Kudryashov <i>et al.</i> "Immunogenicity of Synthetic Conjugates of Lewis <sup>y</sup> Oligosaccharide with Proteins in Mice: Towards the Design of Anticancer Vaccines," <i>Cancer Immunol Immunother</i> , <b>45</b> , 281-286, 1998.
	Kuduk <i>et al.</i> "Synthetic and Immunological Studies on Clustered Modes of Mucin-Related Tn and TF O-Linked Antigens: The Preparation of a Glycopeptide-Based Vaccine for Clinical Trials against Prostate Cancer," <i>J. Am. Chem. Soc.</i> , <b>120</b> , 12474-12485, 1998.



<b>Form PTO-1449</b> (REV. 8-03) 	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket 2003080-0142 (SK-893-B-US)	In re Application No. 10/728,041
<b>INFORMATION</b> <b>DISCLOSURE STATEMENT</b> (Use several sheets if necessary)		Applicant: Danishefsky <i>et al.</i>	
		Filing Date: December 3, 2003	Group: 1642
	Liu <i>et al.</i> , "Structurally Defined Synthetic Cancer Vaccines: Analysis of Structure, Glycosylation and Recognition of cancer Associated Mucin, MUC-1 Derived Peptides," <i>Glycoconjugate Journal</i> , <b>12</b> , 607-617.		
	Paulsen <i>et al.</i> , "Synthesis of the Glycosyl Amino Acids.....," <i>Carbohydrate Research</i> , <b>268</b> , 17-34, 1995		
	Qiu <i>et al.</i> , "Mucin Type Glycopeptides: Synthesis of Core 2, Core 6 and F1- $\alpha$ Building Blocks and Unexpected Reactions," <i>Tetrahedron Letters</i> , <b>38</b> (1), 45-48, 1997.		
	Sames <i>et al.</i> , "Convergent Total Synthesis of a Tumor-Associated Mucin Motif," <i>Nature</i> , <b>389</b> , 587-591, 1997.		
	Toyokuni <i>et al.</i> , "Synthetic Vaccines: Synthesis of a Dimeric Tn Antigen-Lipopeptide Conjugate that Elicits Immune Responses Against Tn-Expressing Glycoproteins," <i>J. Am. Chem. Soc.</i> , <b>116</b> , 395-396, 1994.		
	Zhang, <i>et al.</i> , "Selection of Tumor Agents as Targets for Immune Attack Using Immunohistochemistry: II. Blood Group Related Antigens," <i>Int. J. Cancer</i> , <b>73</b> , 50-56, 1997.		
<b>EXAMINER:</b>			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			